UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
SOUTHEASTERN DIVISION



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| UNITED STATES OF AMERICA, | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| vs. | ) | Case No. 1:99CV140 RWS |
| | ) | |
| SYNTRAX INNOVATIONS, INC., et al., | ) | |
| | ) | |
| Defendants. | ) | |

**MEMORANDUM AND ORDER**

On December 10, 1999, the government filed this civil forfeiture action under the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., seeking the condemnation and destruction of "Triax."[1] Triax, which was being marketed and sold by defendants as a dietary supplement to assist in weight reduction, contains a thyroid hormone called tiratricol. The government's original and amended complaints allege that tiratricol is a misbranded and unapproved drug. Defendants initially contested these allegations and asserted that tiratricol was a dietary supplement, not a drug.

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[1]A second related case, U.S. v. Syntrax Innovations, Inc., Civil Action No. 2:99CV-0956G, was transferred to this district from the United States District Court for the District of Utah and assigned to me as Cause Number 1:99CV140 RWS. Upon joint motion of the parties, that case was consolidated for all purposes with the instant action on March 17, 2000.

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On March 3, 2000, I entered an order granting preliminary injunctive relief with the consent of defendants. That order enjoined defendants from "directly or indirectly manufacturing or distributing any product containing tiratricol, purporting to contain tiratricol, which is labeled as 'Triax,' or any other product containing any T-3 or T-4 thyroid hormone or T-3 or T-4 thyroid hormone analogue" during the pendency of this action.

After summary judgment motions were filed, the government discovered that an investigational new drug application (IND) has been in effect for tiratricol since 1990. This IND precludes tiratricol from being a dietary supplement as a matter of law. 21 U.S.C. § 321(ff)(3)(B)(ii) provides that the term "dietary supplement" does not include "an article authorized for investigation as a new drug . . . for which substantial clinical investigations have been instituted and for which the existence of such investigations have been made public, which was not before such . . . authorization marketed as a dietary supplement or as a food." The undisputed facts demonstrate that: substantial clinical investigations have been instituted for tiratricol; the existence of such investigations have been made public; and, tiratricol was not marketed as a dietary supplement or as a food prior to the authorization of the IND. For this reason, defendants now concede that Triax and any product

containing tiratricol cannot be considered dietary supplements and do not contest entry of summary judgment against them.

However, defendants do object to several of the provisions contained in the government's proposed order of condemnation, forfeiture and permanent injunction. In particular, defendants object to the following proposed provisions: 1) the proposed injunction is overbroad because it is not limited to the marketing and sale of tiratricol; 2) the proposed order is vague because it allegedly enjoins them from "violating the law;" 3) the proposed order grants the FDA the right to conduct inspections of defendants' facilities to ensure compliance with the terms of the permanent injunction without notice; 4) the proposed order requires defendants to pay for the government's investigation and prosecution costs incurred to ensure compliance with the permanent injunction; 5) the proposed order enjoins others "in active concert or participation" with them and is not limited to those involved in the distribution of tiratricol; 6) the proposed order imposes deposition costs and travel expenses upon defendants as a sanction even though the government did not first file a discovery motion on this issue; 7) the proposed order requires that the defendants notify any purchasers of tiratricol that distribution is prohibited; 8) the proposed order allows the FDA to shut down defendants' operations without further order from the Court if it determines that defendants are violating the terms of the

injunction; and 9) the proposed order provides that the FDA's determinations are final and not subject to judicial review.

The government responds that these provisions are necessary to protect the health and are routinely ordered in these kinds of forfeiture cases. I have reviewed all the cases cited by both parties and find that, for the most part, the requested injunctive relief is necessary and has been authorized by many other courts considering these issues. My analysis of the appropriate scope of injunctive relief follows.

Scope of Permanent Injunctive Relief

Defendants do not object to the propriety of a permanent injunction prohibiting the sale and distribution of tiratricol, but contend that the injunctive relief sought by the government is overly broad because it is not limited to the sale and distribution of tiratricol.[2] Instead, the government also seeks to enjoin the sale of products bearing the word Triax on its label or promotional material and "any product labeled as being similar in composition or effect to tiratricol or Triax." After this case was filed, defendants began marketing and selling a product labeled as

[2]The injunction entered today is not limited to sale and distribution activities. However, for ease of reference in the memorandum portion of this opinion, I may refer to the restrained activities as simply "sale and distribution" or some other shorthand version. The use of such shorthand references to the restrained activities should not be read to modify the Order portion of this opinion.

"Triax II." Because Triax II does not contain tiratricol, defendants argue that they should be allowed to continue marketing and selling it. This argument fails.

As the government correctly notes, defendants are marketing Triax II by explicit association with Triax, a misbranded and unapproved new drug. Defendants' marketing materials suggest that this product is an improved version of Triax. In fact, the use of the word Triax implies that there is also tiratricol (an illegal drug) in the product. Defendants have indicated that they intend to continue marketing and selling Triax II unless prohibited from doing so by the terms of this Order. . Because I do not believe the defendants should be permitted to continue profiting, either directly or indirectly, from the sale of an illegal drug, I will enjoin the sale of any products bearing the word "Triax."

Defendants' concern that they will be precluded from selling any products that assist in weight reduction is misplaced. The proposed order does not prohibit defendants from selling products that assist in weight loss; it prohibits the defendants from selling products that reference or draw comparisons between the effects and composition of that product and tiratricol or Triax. I find this provision reasonable and necessary for the same reasons discussed above. This argument would not prevent me from enjoining these activities in any event, because defendants may not "successfully defend against the issuance of an injunction by asserting that the

injunction would drive it out of business." U.S. v. Articles of Drug, 825 F.2d 1238, 1247 (8th Cir. 1987).

Defendants also contend that the proposed injunctive relief is overbroad and vague because it enjoins them from the sale or distribution of: 1) "any product that is a new drug within the meaning of 21 U.S.C. § 321(p), unless and until (1) an approval of an application filed pursuant to 21 U.S.C. § 355(b) is in effect for such product, or (2) an acceptable notice of claimed investigational exemption filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312 is on file for each such product; " and 2) any misbranded drug. Defendants argue that these proscriptions amount to an injunction to simply "follow the law."

While it is true that the terms of an injunction must be specific in terms and reasonably describe the restrained acts, see Fed. R. Civ. P. 65(d), the injunctive relief sought by the government passes this test. It describes with particularity the type of conduct sought to be restrained and does not simply require defendants to "follow the law." This requested relief has been routinely awarded by other courts. See, Articles of Drug, 825 F.2d at 1248 (holding that "the district court did not abuse its discretion in issuing an injunction barring [defendant] from marketing and selling drugs in violation of 21 U.S.C. §§ 331, 352(i)(2)."); U.S. v. Universal Management Services, Inc., 999 F. Supp. 974, 983-84 (N.D. Ohio 1997) (enjoining defendants

from "violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce any article of device that is adulterated or misbranded; (2) violating 21 U.S.C. § 331(k) by causing the adulteration or misbranding of any article of device . . . and (3) violating 21 U.S.C. § 331(p) by failing to register in accordance with 21 U.S.C. § 360."), aff'd, 191 F.3d 750 (6th Cir. 1999), cert. denied, 120 S. Ct. 2740 (2000); U.S. v. Union Cheese Co., 902 F. Supp. 778, 788-89 (N.D. Ohio 1995) (enjoining defendants from "(a) introducing or delivering for introduction into interstate commerce any article of food that is adulterated within the meaning of 21 U.S.C. § 342(a)(1) or § 342(a)(4) while such food or one or more of its components is held for sale after shipment in interstate commerce.").

As for their third objection, defendants correctly note that the inspection authority proposed by the government exceeds the inspection authority granted the FDA under 21 U.S.C. § 374. This fact, however, does not compel the conclusion that the inspection authority proposed by the government is unreasonable or unnecessary. The inspection authority needed by the FDA to ensure that defendants are complying with the terms of my order should be more extensive than the statutory authority granted the FDA to determine whether the FDCA is, in fact, being violated. Here, there is no question that defendants violated the FDCA. Moreover, this Order provides the requisite notice to defendants. This type of relief is routinely

ordered by other courts, see, U.S. v. Vital Health Prods., Ltd., 786 F. Supp. 761, 779 (E.D. Wisc. 1992), aff'd, 985 F.2d 563 (7th Cir. 1993); Union Cheese Co., 902 F. Supp. at 789 (noting that "[t]he inspection authority under this paragraph is apart from, and in addition to, the authority to make inspections under 21 U.S.C. § 374."); Universal Management Services, 999 F. Supp. at 984, and will be awarded here with the modification that the inspections shall be permitted upon presentation of a copy of this Order and appropriate credentials.

Defendants also contend that they should not be forced to pay the costs of inspecting their facilities to ensure compliance with the terms of this Order. Because 21 U.S.C. § 334(e) authorizes an award for court costs and fees, storage and related expenses, this argument fails. The types of expenses and rates charged are set forth in detail in the proposed injunction and will be adopted herein so the defendants will have sufficient notice of the charges and will not be forced, as they have claimed, to "write a blank check" to the government.

Defendants also object to serving a copy of this Order on others "in active concert or participation" with them. I will overrule this objection because I find that it is reasonably necessary to ensure compliance with the terms of my Order. Limiting notification only to those involved in the distribution of tiratricol, as

defendants propose, is insufficient because the injunction bars more than the sale and distribution of tiratricol.

I do agree with defendants, however, that the proposed award of deposition costs and travel expenses as a sanction for failing to participate in discovery is improper. The government did not file a motion to compel this discovery, nor did it file a motion for sanctions for defendants' alleged failure to attend the deposition. Absent a full airing of the facts through appropriate motion practice, I am unwilling to impose such a substantial penalty upon defendants simply because they conceded summary judgment. Therefore, I refuse to award deposition costs and travel expenses to the government in this Order.

I do find, however, that defendants should be required to notify purchasers of tiratricol that its distribution is prohibited. Defendants claim that no notice need be given because it was not requested earlier and because they have committed a "technical violation" of the FDCA. Neither argument is persuasive. Defendants have provided me with no caselaw suggesting that notification should be waived where it was not requested earlier, and my own research has disclosed none, either. Almost all of the forfeiture cases I reviewed required the defendants to notify customers of the injunctive relief, but none of them discussed prior notification as a condition precedent for this requirement. In absence of any authority suggesting

otherwise, I am unwilling to carve out an exception to the consumer notification requirement ordered by most courts in drug forfeiture cases. Nor do I believe that defendants committed a "technical violation." Under these circumstances, I find it necessary to notify purchasers of the ban upon the sale and distribution of Triax and tiratricol.

I also find it necessary to permit the government to shut down the defendants' operations upon a finding of a violation of this Order without further action by this Court. Once again, this relief is routinely ordered by other courts to ensure compliance with the terms of the injunction. See, Union Cheese Co., 902 F. Supp. at 789; Universal Management, 999 F. Supp. at 983; U.S. v. Richlyn Labs., 822 F. Supp. 268, 275 (E.D. Pa. 1993). However, I agree with defendants that this decision, while committed to the sound discretion of the FDA, should not be insulated from judicial review. Accordingly, all decisions conferred upon the government by this Order shall be subject to review, if necessary, under the arbitrary and capricious standard of review set forth in 5 U.S.C. § 706 (2)(A). See Union Cheese Co., 902 F. Supp. at 790.

Motion for Contempt

The government has also filed a motion to adjudge defendants in civil contempt of the preliminary injunction entered on March 3, 2000. As discussed

above, defendants have been marketing and selling a product called "Triax II." The preliminary injunction prevents them from "directly or indirectly manufacturing or distributing any product containing tiratricol, purporting to contain tiratricol, which is labeled as 'Triax,' or any other product containing any T-3 or T-4 thyroid hormone or T-3 or T-4 thyroid hormone analogue" during the pendency of this action. The government contends that the marketing and sale of "Triax II" directly violates the terms of the injunction and seeks disgorgement of all proceeds from the sale of this product, attorneys fees and a conditional fine as sanctions for defendants' alleged contempt.

Defendants contend that sanctions are not warranted because the language of the preliminary injunction is ambiguous, and the government knew about sales of Triax II before the preliminary injunction was entered but did not indicate that their continued sale of this product would be prohibited. Moreover, defendants contend that sanctions are inappropriate because of the government's delay in filing its motion for contempt. The FDA conducted an inspection of the defendants' facility in June of 2000. Although the FDA was given information about sales of Triax II at that time, it did not indicate that sales of the product were barred under the injunction until November of 2000 and did not seek sanctions until December of

2000. The government responds that it wanted to confirm the sales of Triax II by deposing defendant Cornelius before bringing its motion for contempt.

The parties indicated at the January 17, 2001 status conference in this case that they wanted me to decide this issue without the benefit of a hearing. I must exercise my discretion when deciding whether to adjudge a party in civil contempt of my orders and award sanctions. After carefully considering all the relevant factors, I will decline to find defendants in civil contempt. I agree that the language of the preliminary injunction, which was proposed by the parties and presented to the Court for review, is probably not as clear as it could have been. The wording of the instant order, however, avoids this potential misunderstanding by restraining defendants from marketing and selling "any product bearing the word 'Triax' on its labeling or promotional material." This obviously prohibits defendants from selling Triax II (or any other Triax product) as of the date of this Order. I also find that the government's prior knowledge of this activity and its refusal to bring defendants' conduct before the Court in a timely fashion militates against an award of sanctions.

Accordingly, based upon the reasons set forth herein,

**IT IS HEREBY ORDERED** that plaintiff's second motion for summary judgment [#35] is granted, and plaintiff's motion for sanctions [#40] is denied.

**IT IS FURTHER ORDERED** that all other pending motions are denied as moot.

**IT IS FURTHER ORDERED, ADJUDGED and DECREED**:

1. This Court has jurisdiction over the subject matter herein and over all persons and parties to this action, and the complaints state a cause of action against the defendants under the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq.

2. The seized articles are drugs within the meaning of the FDCA, 21 U.S.C. § 321(g)(1), that may not be introduced or delivered for introduction into interstate commerce pursuant to 21 U.S.C. § 355(a) because they are new drugs within the meaning of 21 U.S.C. § 321(p) and no approvals of applications filed pursuant to 21 U.S.C. § 355(b) are in effect for such drugs.

3. The seized articles are drugs within the meaning of the FDCA, 21 U.S.C. § 321(g)(1), that are misbranded while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of the FDCA, 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use and they are not exempt from such requirement under 21 C.F.R. § 201.115 because the articles are unapproved new drugs.

4. The seized articles are hereby condemned pursuant to 21 U.S.C. § 334(a) and forfeited to the United States.

5. Pursuant to 21 U.S.C. § 334(d), the United States Marshal for the Eastern District of Missouri shall forthwith destroy the condemned articles held within this district and make due return to this Court.

6. In accordance with the Order of Consolidation filed March 17, 2000, in the United States District Court for the District of Utah in Civil Action No. 2:99CV-0956G, which Order provided that the articles seized pursuant to that action would remain in the custody of the United States Marshals pending further order by this Court, and

pursuant to 21 U.S.C. § 334(d), the United States Marshal for the District of Utah is directed to destroy forthwith the condemned articles held within Utah and make due return to this Court.

7. Pursuant to 21 U.S.C. § 334(e), the United States shall recover from the individual and corporate defendants all court costs and fees, storage costs, and other proper expenses, including the cost of destroying the condemned articles. The individual and corporate defendants shall pay any costs described in this paragraph within fifteen (15) calendar days of their receipt of notice of such costs.

8. Within twenty (20) calendar days of the entry of this Order, the individual and corporate defendants shall destroy under FDA supervision any product containing tiratricol, purporting to contain tiratricol, bearing the word "Triax" on its labeling or promotional material, or which is labeled as being similar in composition or effect as tiratricol or Triax, which is within their possession or control and shall, within thirty (30) calendar days of the entry of this Order, provide proof of destruction to the Office of the District Director, Kansas City District Office, Food and Drug Administration (FDA), 11510 West 80th Street, P.O. Box 15905, Lenexa, KS 66285-5905. The United States shall recover from the individual and corporate defendants any costs incurred in supervising the destruction of products pursuant to this paragraph at the rates specified in paragraph 16. The defendants shall pay any costs due under this paragraph within fifteen (15) calendar days of their receipt of notices of such costs.

9. The individual and corporate defendants violate 21 U.S.C. § 331(d), by introducing and delivering and causing the introduction and delivery for introduction into interstate commerce of drugs that are new drugs within the meaning of 21 U.S.C. § 321(p) and that are not approved and are therefore in violation of 21 U.S.C. § 335(a).

10. The individual and corporate defendants violate 21 U.S.C. § 331(a), by introducing, delivering for introduction, and causing the introduction and delivery for introduction into interstate commerce of drugs which are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

11. The individual and corporate defendants violate 21 U.S.C. § 331(k) by causing the misbranding of drugs within the meaning of 21 U.S.C. § 352(f)(1) while such drugs are held for sale after shipment in interstate commerce.

12. Defendants, Syntrax Innovations, Inc., a corporation, and Derek W. Cornelius, an individual, and each and all of their officers, agents, servants, employees, and attorneys, and any and all persons in active concert or participation with any of them who have received actual notice of this Order by personal service or otherwise, are permanently and enjoined under 21 U.S.C. § 332(a) from directly or causing to be done any of the following acts:

A. Introducing or delivering for introduction into interstate commerce, or receiving in interstate commerce and delivering or proffering for delivery, any product containing tiratricol, any product purporting to contain tiratricol, any product bearing the word "Triax" on its labeling or promotional material, or any product labeled as being similar in composition or effect to tiratricol or Triax, unless and until (1) an approval application filed pursuant to 21 U.S.C. § 335(b) is in effect for each such product, or (2) an acceptable notice of claimed investigational exemption filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312 is on file for each product;

B. Introducing or delivering for introduction into interstate commerce any product that is a new drug within the meaning of 21 U.S.C. § 321(p), unless and until (1) an approval of an application filed pursuant to 21 U.S.C. § 355(b) is in effect for each such product, or (2) an acceptable notice of claimed investigational exemption filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312 is on file for each such product;

C. Introducing or delivering for introduction into interstate commerce any misbranded drug, within the meaning of 21 U.S.C. § 352; and

D. Misbranding any drug, within the meaning of 21 U.S.C. § 352, while such drug is held for sale after shipment of one or more components in interstate commerce.

13. Defendants shall post a copy of this Order in a conspicuous location at all of their places of business within ten (10) calendar days of the entry of this Order, and shall ensure that the Order remains posted for a continuous period of one year.

14. Within ten (10) calendar days of the entry of this Order, the individual and corporate defendants shall serve a copy of this Order, by personal service or registered mail, return receipt requested, on each of their officers, agents, servants, employees, and attorneys, and any and all persons in active concert or participation with any of them (hereinafter, collectively referred to as "associated persons"). Within twenty (20) calendar days of the entry of this Order, defendants shall provide the FDA District Director, Kansas City District Office, and the plaintiff's attorneys with an affidavit of compliance, signed by defendant Cornelius and by an authorized official on behalf of defendant Syntrax Innovations, Inc., stating the fact and manner of compliance with this paragraph, listing the names, addresses, and positions of all persons so notified, and attaching a copy of the executed mail return receipts. In the event that any of the defendants become associated, at any time after the entry of this Order, with any additional associated person(s), defendants immediately shall provide a copy of this Order, by personal service or registered mail, return receipt requested, to such associated person(s). Each time any of the defendants become associated with any such additional associated person pursuant to this paragraph, and within twenty (20) calendar days of doing so, the defendants shall also provide to the FDA, District Director, Kansas City District Office, and affidavit, signed by defendant Cornelius and an authorized official on behalf of defendant Syntrax Innovations, Inc., stating the fact and manner of compliance with this paragraph, listing the names, addresses, and positions of all persons so notified, and attaching a copy of the executed mail return receipts.

15. FDA investigators shall be permitted to make inspections of defendants' facilities as FDA deems necessary to ensure continuing

compliance with the terms of this Order, and shall be permitted access during such inspections to all equipment, finished and unfinished articles of drug and food (including dietary supplements), and all labeling, manufacturing and shipping records, files, papers, and all records pertaining to Syntrax Innovations Inc., in defendants' possession, custody, or control, or that are accessible by defendants, and to take photographs, make video tape recordings, and make copies of records. Such inspections shall be authorized upon presentation of a copy of this Order and appropriate credentials. The inspection authority granted by this Order is apart from, and in addition to, the authority to make inspections under 21 U.S.C. § 374.

16. The individual and corporate defendants shall reimburse FDA for the costs of all FDA inspections, supervision, analyses, evaluations, and examinations that FDA deems necessary to evaluate the individual and corporate defendants' compliance with this Order, including the costs of inspection, analysis, travel and subsistence expenses, if necessary. The costs of such inspections shall be borne by the individual and corporate defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Order is signed, these rates are: $59.50 per hour and fraction thereof per representative for inspection and supervision work other than laboratory and analytical work, $71.79 per hour or fraction thereof per representative for laboratory and analytical work, $0.345 per mile for travel expenses by automobile, government rate or the equivalent for travel by air, and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day per representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance activities are modified, these rates shall be increased or decreased without further order of the Court. In addition, if any defendant violates this Order and is found in civil or criminal contempt thereof, that defendant shall, in addition to any other remedies, reimburse plaintiff for its attorney fees (including overhead), travel expenses incurred by attorneys and witnesses, investigational, evaluation, and analytical expenses, expert witness fees, and court costs relating to such contempt proceedings. The defendants shall pay any costs due under

this paragraph fifteen (15) calendar days of their receipt of notice of such costs.

17. The individual and corporate defendants shall notify, by letter, each person, customer, company, corporation, or any other entity who, to the individual and corporate defendants' knowledge or belief, has received, or may have received, any Syntrax product containing tiratricol that, pursuant to a decree of this Court, the defendants may no longer distribute Triax or any product containing tiratricol because they are misbranded and unapproved "new drugs" and that any continued distribution of those drug products is a violation of this Order and the Federal Food, Drug and Cosmetic Act. This letter must be submitted to and approved, in writing, by the FDA District Director, Kansas City District Office, prior to its distribution. The letter must be submitted to the FDA District Director for review within fifteen (15) calendar days of the date of entry of this Order.

18. Within thirty (30) calendar days of the date of entry of this Order, the individual and corporate defendants shall provide the FDA District Director, Kansas City District Office, with an affidavit identifying the names, positions and addresses of all persons notified pursuant to paragraph 17. The affidavit shall be signed by defendant Cornelius and by an authorized official on behalf of Syntrax Innovations, Inc., and shall include a copy of all letters sent evidencing the individual and corporate defendants' compliance with paragraph 17 of this Order.

19. The individual and corporate defendants immediately shall cease manufacturing, packing, processing, distributing, promoting, holding, and labeling, directly or indirectly, any article if, based on the results of an inspection, investigation, analysis of a sample or samples, or other information, FDA notifies the individual and corporate defendants in writing that their manufacturing, packing, processing, distributing, promoting, holding, or labeling of such article is in violation of this Order.

20. Any cessation of operations pursuant to paragraph 19 shall go into effect without further order from this Court and shall continue until the individual and corporate defendants receive written notification from

FDA that the individual and corporate defendants' manufacturing, packing, processing, distributing, promoting, holding, and labeling of such article is in compliance with this Order.

21. If, based on the results of an inspection, investigation, analysis or a sample or samples, or other information, FDA determines that the individual or corporate defendants have shipped one or more articles of drug in violation of the FDCA or this Order, FDA may, as it deems necessary, order the defendants to recall such articles. Any such recall shall be conducted by the defendants in accordance with recall procedures set forth in Chapter 21, Code of Federal Regulations, Part 7. In the event that FDA requests a recall under this paragraph, the individual and corporate defendants promptly shall provide the FDA District Director, Kansas City District Office, with any and all information that the Director deems necessary to monitor the progress of the recall.

22. The individual and corporate defendants shall, in writing, notify FDA at least thirty (30) calendar days before any change in ownership, character, or name of their business, including reorganization, relocation, dissolution, assignment, or sale resulting in the emergence of a successor entity or corporation; the creation or dissolution of subsidiaries or any other change in the corporate structure or identity of Syntrax Innovations, Inc.; or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect obligations arising out of this Order. The individual and corporate defendants shall serve a copy of this Order on any prospective successor or assign no later than thirty (30) calendar days prior to such sale or change in business, and shall furnish the FDA District Director, Kansas City District Office and plaintiff's attorneys with an affidavit of compliance with this paragraph within fifteen (15) calendar days of such sale or change in business. Pursuant to Rule 65(d) of the Federal Rules of Civil Procedure, this Order shall apply to the individual and corporate defendants and to each and all of their officers, agents, servants, employees, and attorneys, and any and all persons in active concert or participation with any of them who have received actual notice of this Order by personal service or otherwise.

23. All decisions conferred upon FDA in this Order are committed to the discretion of FDA, which shall be reviewed, if necessary, under the arbitrary and capricious standard of review set forth in 5 U.S.C. § 706(2)(A).

24. This Court retains jurisdiction over this action for the purpose of enforcing or modifying this Order and for the purpose of granting such additional relief as may hereafter appear necessary or appropriate.

25. All correspondence with FDA pursuant to this Order shall be sent to the FDA District Director, Kansas City District Office.

26. Except as provided above, the parties shall bear their own costs and attorneys' fees in this action.

RODNEY W. SIPPEL
UNITED STATES DISTRICT JUDGE

Dated this 14th day of February, 2001.

UNITED STATES DISTRICT COURT - EASTERN MISSOURI
INTERNAL RECORD KEEPING

**** CONSOLIDATED CASE ****

AN ORDER, JUDGMENT OR ENDORSEMENT WAS SCANNED, FAXED AND/OR MAILED TO THE FOLLOWING INDIVIDUALS ON 02/15/01 by mschaefe
1:99cv140 USA vs 11 Cases

21:841 Forfeiture Property-Drugs

IF THIS IS A FINAL JUDGMENT OF FORFEITURE YOU MUST SEND THREE CERTIFIED COPIES TO THE U.S. MARSHALS.

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